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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/681,018	10/08/2003	Joan M. Fallon	8016-1 CIP CON	6224

24222 7590 08/07/2007

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EXAMINER	
JIANG, DONG	
ART UNIT	**PAPER NUMBER**
1646	

MAIL DATE	DELIVERY MODE
08/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/681,018	FALLON, JOAN M.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-35 and 42-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-35 and 42-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED OFFICE ACTION

Applicant's amendment filed on 18 May 2007 is acknowledged and entered. Following the amendment, claims 36-41 are canceled, claims 23, 27, 33, 34 and 42 are amended, and the new claims 43 and 44 are added.

Currently, claims 23-35 and 42-44 are pending and under consideration.

Withdrawal of Objections and Rejections:

The rejection of claims 27, 31, 33 and 34 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of applicant's amendment.

Formal Matters:

Claims 23 and 42-44 are objected to for the following informalities, appropriate correction is required for each item:

The word "chymotryspin" in the claims 23, 42 and 44 should be "chymotrypsin".

Claim 43, "effective amount of digestive improves ..." should be "effective amount of digestive *enzymes* improves ..."

New Matter Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 44 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. While the specification teaches that the treatment of autistic patients with digestive enzymes improves symptoms of the patients, applicants have not pointed out, nor can the Examiner locate, the basis in the specification for a method of *treating protein deficiency* in an individual having an autistic disorder with digestive enzymes.

Double Patenting Rejections:

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 23, 42 and 43 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 7 of U.S. Patent No. 6,632,429. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

The present claim 23 is drawn to a method for treating autistic disorder with digestive enzymes, wherein the disorder is characterized by an abnormal fecal chymotrypsin level. Claims 1 and 7 of the patent encompasses or is directed to a method for treating autistic disorder with digestive enzymes, wherein the fecal chymotrypsin level of the individual is less than normal. The active ingredient of digestive enzymes is the same as that of the instant claim 23. Although the present claim 23 does not specifically recite the method step of comparing a fecal chymotrypsin level, as that in claims 1 and 7 of the patent, it requires that the disorder is characterized by an abnormal fecal chymotrypsin level. Therefore, the required patient population (with respect to autism) of the claims of the patent is the same as that of the instant claim 23, and the specific step of comparing the fecal chymotrypsin level is one way to

characterize an abnormal fecal chymotrypsin level. With respect to the present claims 42 and 43, the recited effect of promoting protein digestion to improve a symptom of the disorder, it would be the inherent property for claims 1 and 7 of the patent as the same active ingredient is used for the same patients. Thus, the conflicting claims are not patentably distinct from each other.

Rejections under 35 U.S.C. 112:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23-35 and 42 remain rejected and the new claim 43 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited in scope to a method for treating an individual having an autistic disorder having *decreased* fecal chymotrypsin levels, does not reasonably provide enablement for claims to a method for treating autictic individuals having an "abnormal" fecal chymotrypsin level (claims 23 and 42, for example). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with the claims.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The independent claims 23 and 42 recite "characterized by an *abnormal* fecal chymotrypsin level", which reads on either increase or decreased level of chymotrypsin. However, the specification merely teaches that a method of treatment with digestive enzymes for autistic individuals having *decreased* fecal chymotrypsin levels (Example 6), and provides no evidence or working examples indicating otherwise (*increased* fecal chymotrypsin levels). Therefore, while the specification provide enabling disclosure for a method of treating autistic individuals having *decreased* fecal chymotrypsin levels with digestive enzymes, it does not

reasonably provide enablement commensurate in scope with claims to a method for treating autistic individuals characterized by an *abnormal* fecal chymotrypsin levels as .

Due to the lack of direction/guidance presented in the specification regarding *increased* fecal chymotrypsin levels in the claimed condition, the absence of working examples directed to same, the complex nature of the invention, and the breadth of the claims which embrace both decrease and increased fecal chymotrypsin levels, the specification does not enable any person skilled in the art to use the claimed invention in its full scope.

Rejections Over Prior Art:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 23-35 and 42-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beck et al. (US6,020,310, provided by applicants), and further in view of Sipos (US4,079,125).

Beck discloses that there are two subgroups of autistic patients, distinguished on the basis of gastrointestinal symptoms, blood secretin levels, the increase in serotonin level after secretin injection and the quantity and quality of fluid produced for secretin stimulation, and that there is high prevalence of other gastrointestinal abnormalities including inflammation in the esophagus, *digestive enzyme deficiencies* in children with autistic behavior, which supports a relationship between the presence of gastrointestinal dysfunctions and autism (column 4, lines 56-65). Beck indicates that patients with chronic, non-infectious diarrhea with unclear etiology were analyzed by the full upper GI work-up including biopsies for histology measurement of the digestive enzymes of the small intestine and the pancreas (including chymotrypsin) (column 10, lines 12-17, and 36-40).

Beck does not explicitly mention treating autism having digestive enzyme deficiencies with digestive enzymes.

Sipos teaches digestive enzyme-containing compositions, which are capable of withstanding hours of exposure to gastric fluids while protecting the biological activity of the enzymes (abstract), and that the principal active agents in the composition are enzymes including such pancreatic enzymes as the proteases, for example trypsin, chymotrypsin (column 5, lines 20-23). Further, Sipos teaches that the total amount of the composition required to be administered to an enzyme deficient patient will vary with the severity of the condition and the amount of food ingested, and the compositions is administered with each meal (column 9, lines 10-16).

With respect to claims 23, 32, 35, 42 and 43, it would have been obvious to the person of ordinary skill in the art at the time the invention was made to treat autism with Sipos's digestive enzyme-containing compositions as Beck teaches that there is high prevalence of gastrointestinal abnormalities including digestive enzyme deficiencies in children with autistic behavior (note, the fecal chymotrypsin level in these patients would be inherently low because of the enzyme deficiency). The person of ordinary skill in the art would have been motivated to do so for disease treatment, and reasonably would have expected success because Beck has demonstrated that autistic patients have digestive enzyme deficiencies, and Sipos has demonstrated that the digestive enzyme-containing compositions are capable of withstanding hours of exposure to gastric fluids, and remaining the biological activity of the enzymes.

With respect to claims 24-30, they recite the improvement of specific symptoms, which would be inherent property of the method obvious over the prior art as the active ingredient, method steps and patient population are the same as that taught by the prior art references.

With respect to the specific limitations of dosage (claim 31), "determined according to the age and weight of the individual" (claim 33), and frequency of administering the enzyme (claim 34) in claims 31, 33 and 34, Sipos teaches that the total amount of the composition required to be administered to an enzyme deficient patient will vary with the severity of the condition and the amount of food ingested. Given the state of the art at the time the invention was filed, and the teachings of Sipos, determining the proper dosage and therapeutic regimens for any particular patientis well within the skilled artisan's purview. Further, given the fact that "approximately 4,000 to approximately 60,000" in the present claim (claim 31) represents a broad dose range, and the fact that there is no specific dosage is recited in claims 33 and 34, an

artisan would have to determine a specific therapeutically effective amount suitable for each specific patient within the scope of sound medical judgment, as the dose level will depend upon various factors. Therefore, the claimed invention, taken as a whole, is considered prima facie obvious over the Beck and Sipos references.

Conclusion:

No claim is allowed.

Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Dong Jiang, Ph.D.
Patent Examiner
AU1646
7/24/07